**UNITED STATES DISTRICT COURT**
**EASTERN DISTRICT OF NEW YORK**

----------X

BARBARA DAVIDS

Plaintiff,

-against-

NOVARTIS PHARMACEUTICALS CORPORATION,

Defendant.

----------X

**MEMORANDUM OF DECISION AND ORDER**

06-CV-431 (ADS)(WDW)

**APPEARANCES:**

**Valad & Vecchione, PLLC**
Attorneys for the Plaintiff
3863 Plaza Drive
Fairfax, VA 22030
By: Bart T. Valad, Esq.
John J. Vecchione, Esq., Of Counsel

**Terrence J. Sweeney, Esq.**
Attorney for the Plaintiff
225 Broadway
New York, NY 10007

**Lally & Misir, LLP**
Attorneys for the Plaintiff
220 Old Country Road
Mineola, NY 11501
By: Demorah N. Misir, Esq., Of Counsel

**Hollingsworth LLP**
Attorneys for the Defendant
1350 I Street, NW, 9th Floor
Washington, D.C. 20005
By: Anne Marla Friedman, Esq.
Bruce J. Berger, Esq.
Jared Wiesner, Esq.
Katharine R. Latimer, Esq.
Robert E. Johnston, Esq., Of Counsel

**Rivkin Radler LLP**
Attorneys for the Defendant
926 Rxr Plaza
Uniondale, N.Y. 11556
By: Jesse J. Graham, II, Esq.
David Richman, Esq., Of Counsel

**SPATT, District Judge.**

Barbara Davids ("Ms. Davids" or "the Plaintiff") commenced this products liability action against Novartis Pharmaceuticals Corporation ("Novartis", "NPC", or "the Defendant"), alleging that the Novartis drug Zometa caused her to develop a condition referred to as bisphosphonate-related osteonecrosis of the jaw. Presently before the Court are seven Daubert motions by Novartis to exclude testimony by the Plaintiffs' retained and non-retained experts and a motion by Novartis for summary judgment dismissing the Plaintiff's complaint pursuant to Federal Rule of Civil Procedure 56. The Court now rules on all of these motions.

## I. BACKGROUND

### A. Factual Background

In August of 2001, Barbara Davids was diagnosed with Stage I breast cancer. Initially, Dr. Sheehy-Milano, Ms. Davids's oncologist, prescribed a number of treatments, including Cytoxan, Methotrexate, chemotherapy, radiation therapy, cortiscosteroids, and hormonal therapy. In 2001, Dr. Anthony Ardito, Ms. Davids's primary care physician, prescribed weekly Fosamax to treat Ms. Davids's osteoporosis. Fosamax is an oral bisphosphonate drug manufactured by Merck, which is also alleged to be linked to the development of osteonecrosis of the jaw.

In September of 2003, Ms. Davids's cancer metastasized to her bones and Dr. Sheehy-Milano prescribed a drug called Femara. Subsequently, beginning on October 8, 2003, Dr.

Sheehy-Milano began infusing Ms. Davids with Zometa, an intravenous bisphosphonate drug manufactured by the defendant Novartis Pharmaceuticals Corporation.

Zometa is a bisphosphonate prescribed to patients with, among other conditions, certain kinds of cancer that have metastasized to the bones. Zometa may reduce or delay bone fractures or pressure on the spinal cord that can result from bone damages from these advanced cancers. It is prescribed by oncologists to limit and, according to Novartis, prevent, the harmful effects of disease induced bone loss, including debilitating skeletal events such as bone fractures or spinal cord compression. The parties greatly dispute whether Zometa is the "standard of care" in medicine to treat bone cancers, and whether Zometa has been shown to slow the spread of the underlying cancer itself.

In February 2002, the Food and Drug Administration ("FDA") approved Zometa as safe and effective to treat multiple myeloma and bone metastases from solid tumors. Although the FDA also approved the label information for Zometa, the parties dispute whether Novartis knew of and withheld information from the FDA, namely, that certain users of Zometa were at risk of developing a condition called osteonecrosis of the jaw ("ONJ"). Osteonecrosis of the jaw is a type of bone disease that causes damage or death to areas in the jaw bone. Ms. Davids alleges that she has developed a type of ONJ referred to as bisphosphonate-related osteonecrosis of the jaw ("BRONJ").

It is undisputed that Zometa remains on the market as an FDA-approved drug, with labeling approved by the FDA. However, the Plaintiff argues that this is only true to the extent that the FDA has required stronger safety information regarding ONJ, and the removal of false language placed on the label by Novartis regarding "well documented" risk factors.

Ms. Davids received Zometa infusions from Dr. Sheehy-Milano approximately once a month between October of 2003 and January 2005. Her last infusion was on January 6, 2005. During this time, Dr. Sheehy-Milano also treated Ms. Davids for anemia; took her off Femara; prescribed Faslodex; and Ms. Davids underwent additional radiation therapy.

Relevant to the instant case is Ms. Davids's dental history, and the extent to which her pre-existing dental problems contributed to her development of osteonecrosis of the jaw and/or the decisions by her doctors to prescribe Zometa. Dr. Perry Perzov has been Ms. Davids's general dentist since 1989, although Ms. Davids admits to having a history of periodontal disease in the five years preceding her treatment by Dr. Perzov. On November 11, 1995, Dr. Perzov extracted Ms. Davids's tooth # 17. In addition, prior to Ms. Davids's diagnosis of breast cancer in 2001, Dr. Perzov treated Ms. Davids for symptoms relating to the lower right mandible and upper right maxilla with periapical pathology associated with tooth #5; food trapping between teeth # 18, #19, and #20; and a loose tooth, #29 with complete bone loss.

On July 1, 2003, three months before beginning Zometa, Ms. Davids visited Dr. Perzov and had a dental examination at which Dr. Perzov made adjustments to Ms. Davids's teeth numbers 19 and 20. At that time, Dr. Perzov noted that Ms. Davids was "OK" with "aesthetics" and "comfort". Ms. Davids continued to visit Dr. Perzov throughout the time she was being treated with Zometa by Dr. Sheehy-Milano and Fosamax by Dr. Ardito. In July 2004, while still being treated with Zometa and Fosamax, Dr. Perzov extracted teeth #6, #7, #8, #9, # 10, and #11 in the upper jaw ("maxilla"), which healed without incident, and he fitted Ms. Davids for a full upper denture.

In November 2004, Ms. Davids complained to Dr. Perzov of soreness and pain in her left lower jaw ("mandible"). Upon inspection, Dr. Perzov discovered a 2.5mm diameter lesion and a

bony spicule on the lingual mucosa in the area of tooth #17, which he removed. After the area failed to heal, Dr. Perzov referred Ms. Davids to Dr. Leonard Hoffman, an oral and maxillofacial surgeon. According to Ms. Davids, and highly disputed by Novartis, the procedure to remove the bony spicule in 2004 triggered Ms. Davids's BRONJ.

On January 5, 2005, Ms. Davids met with Dr. Hoffman, and presented with a three month history of exposed bone from the front of her mouth to tooth #18. On January 12, 2005, Dr. Hoffman prescribed Clindamycin as treatment. It is undisputed, that at some point in 2003 and 2004, Dr. Hoffman learned anecdotally about a "possible" association between ONJ and bisphosphonate drugs such as Zometa and Fosamax from Dr. Salvatore Ruggiero. Ms. Davids disputes the characterization of "possible" as misleading. Based on the anecdotal evidence of a relationship between bisphosphonates and ONJ, as well as his examination of Ms. Davids, Dr. Hoffman diagnosed Ms. Davids with BRONJ.

On January 11, 2005, after consulting with Dr. Hoffman about the Plaintiff's jaw problems, Dr. Sheehy-Milano decided to end Ms. Davids's Zometa prescription. Although Ms. Davids discontinued her injections of Zometa, she continued to receive weekly Fosamax therapy as prescribed by Dr. Ardito until June of 2006. Following the discontinuance of Zometa, Dr. Sheehy-Milano has prescribed a number of different drugs and therapies to treat Ms. Davids's cancer, which has spread to other sites in her bones.

In addition to treatment by Dr. Hoffman, following the discontinuance of Zometa, Ms. Davids was also treated for her jaw problems by another oral and maxillofacial surgeon, Dr. Ronald Schneider. Following Dr. Schneider's retirement, beginning in October 2007, Ms. Davids began visiting with Dr. Salvatore Ruggiero to continue treatment of her jaw problems.

Dr. Ruggiero diagnosed Ms. Davids with Stage III BRONJ, which is the most advanced form of the disease.

On February 2, 2006, the Plaintiff commenced this lawsuit against Novartis, alleging that Zometa caused her to develop BRONJ. The Third Amended Complaint in this action seeks compensatory damages under the theories of: (1) strict liability; (2) negligent manufacture; (3) negligent failure to warn; (4) breach of express warranty; and (5) breach of implied warranty. The Plaintiff also seeks punitive damages. In addition to the current lawsuit, the Plaintiff has filed a lawsuit against Merck, the manufacturer of Fosamax. See Davids v. Merck & Co., Inc., No. 06-CV-13401 (S.D.N.Y. Nov. 20, 2006).

**B. Procedural History and Prior Decisions**

This is the third case to come before this court by a plaintiff who allegedly developed bisphosphonate-related osteonecrosis of the jaw from the use of an intravenous-bisphosphonate drug manufactured by Novartis ("the Davids case"). The other two cases were Deutsch v. Novartis Pharmaceuticals Corporation, No. 09-CV-4677 ("the Deutsch case"), and Forman v. Novartis Pharmaceuticals Corporations, No. 09-CV-4678 ("the Forman case"). All three of these cases were initially filed before this Court in 2006, and on May 24, 2006, were consolidated with similar cases pursuant to the Multi–District Litigation Act and transferred to United States District Judge Todd J. Campbell in the Middle District of Tennessee ("the MDL court").

**1. The Deutsch case and the Forman case**

In the MDL court, the Deutsch and Forman cases were part of what was known as "Wave I-A". In conjunction with the Wave I-A cases, the MDL court rendered decisions on : (1) Novartis's Motion for Summary Judgment Based upon a Failure of General Causation Proof

under Daubert ("Causation Summary Judgment Motion"); (2) Novartis's Motion for Summary Judgment on the Adequacy of its Aredia and Zometa Warnings ("Warnings Summary Judgment Motion"); (3) the Daubert motions by Novartis to exclude the expert testimony of Dr. Keith Skubitz, Dr. James Vogel, Professor Wayne Ray, Ph.D. ("Prof. Ray"), Dr. Talib Najjar, Dr. Robert Marx (consisting of two separate motions, one to exclude his litigation-wide testimony and one to exclude his case-specific testimony in the Forman case), Dr. Suzanne Parisian, Dr. Robert Fletcher, Dr. Paul Hanson, Dr. John Hellstein, and the non-retained experts in the Deutsch and Forman cases; (4) the Daubert motions by the Deutsch and Forman plaintiffs' to exclude the testimony on the causation of BRONJ by Novartis's oncologic experts; (5) the Motion for Summary Judgment by Novartis in the Deutsch case; and (6) the Motion for Summary Judgment by Novartis in the Forman case.

By orders dated August 13, 2009, the MDL court denied both the Causation Summary Judgment Motion, In re Aredia and Zometa Prods. Liab. Litig. ("MDL Causation Order"), No. 06–MD–1760, 2009 WL 2497536 (M.D. Tenn. Aug. 13, 2009) and the Warnings Summary Judgment Motion, In re Aredia and Zometa Prods. Liab. Litig., No. 06–MD–1760, Docket # s 2766, 2767 ("MDL Warnings Order"). In addition, the MDL court either denied or denied in part and mooted in part the Daubert motions by Novartis to exclude the expert testimony of Dr. Skubitz, Dr. Vogel, Dr. Najjar, and the litigation-wide and case specific testimony of Dr. Marx. Finally, the MDL court mooted in their entirety the motions by Novartis to exclude the expert testimony of Dr. Hanson, Dr. Hellstein, Prof. Ray, Dr. Fletcher, Dr. Parisian, as well as the Deutsch and Forman plaintiffs' non-retained experts, and the Deutsch and Forman plaintiffs' motions to exclude the expert testimony on the causation of BRONJ by the Novartis oncologic experts.

Following the resolution of these motions, on September 25, 2009, the MDL court remanded the Deutsch case and the Forman case back to this Court for trial. Although the parties agreed that New York law governed the substantive causes of action, the parties disputed the applicable governing law as to the issue of punitive damages. On July 16, 2010, this Court issued a decision holding that New Jersey law applied to the issue of punitive damages. See Deutsch v. Novartis Pharms. Corp. ("Punitive Damages Order I"), 723 F. Supp. 2d 521 (E.D.N.Y. 2010).

Subsequently, Novartis filed Daubert motions to exclude the expert testimony of: (1) Dr. Skubitz, (2) Dr. Vogel, (3) Dr. Marx, (4) Prof. Ray, (5) Dr. Fletcher, (6) Dr. Parisian, (7) the Deutsch and Forman plaintiffs' non-retained experts, including Dr. Salvatore Ruggiero, with regard to causation, (8) Dr. Hanson, and (9) Dr. Hellstein. The Daubert motions with respect to Dr. Hanson and Dr. Hellstein were subsequently withdrawn on consent.

On March 8, 2011, this Court issued a fairly lengthy and detailed decision granting in part and denying in part Novartis's Daubert motions. See Deutsch v. Novartis Pharms. Corp. ("Deutsch Daubert Order"), 768 F. Supp. 2d 420 (E.D.N.Y. Mar. 8, 2011). Before addressing the substance of Novartis's motions, the Court held that it would "not decide any issues previously presented to and denied by the MDL court" and "to the extent Novartis' argue[d] that an opinion is inadmissible because it relies on a retrospective non-controlled study, the Court finds that these arguments go to the weight and not the admissibility of the opinions". 768 F. Supp. 2d at 429, 430. With respect to the motion by Novartis to exclude the testimony of Dr. Parisian, the Court held that, as to certain opinions, a Daubert hearing was necessary to determine their admissibility. The Court held the above-referenced Daubert hearing on April 11, 2011 and May 2, 2011. In a subsequent order dated June 22, 2011, the Court held that "Dr.

Parisian's methodology is reliable and that there is no risk of prejudice to NPC by permitting her testimony". See Forman v. Novartis Pharms. Corp. ("Parisian Daubert Order"), 794 F. Supp. 2d 382, 383 (E.D.N.Y. 2011).

In addition, Novartis filed a motion in both the Deutsch and Forman cases seeking to prevent the plaintiffs from pursuing punitive damages on the grounds that: (1) federal law preempted the plaintiffs from obtaining punitive damages under the relevant New Jersey statutes; (2) the plaintiffs lacked standing to pursue punitive damages under the relevant New Jersey statutes; and (3) the plaintiffs' evidence was insufficient to raise a genuine issue of material fact as to whether they are entitled to punitive damages. On June 20, 2011, the parties in the Deutsch case entered into a stipulation of settlement on the record.

On June 27, 2011, the Court issued a decision only in the Forman case, finding that federal law did not preempt the plaintiff's right to pursue punitive damages under the relevant New Jersey statutes, and that the plaintiff did not lack standing to seek punitive damages. See Forman v. Novartis Pharms. Corp. ("Punitive Damages Order II"), 793 F. Supp. 2d 598 (E.D.N.Y. 2011). In addition, the Court reserved decision as to whether a genuine issue of material fact existed to permit an award of punitive damages.

Following two days of jury selection, on February 29, 2012, the parties in the Forman case entered in to a stipulation of settlement.

**2. The Davids Case**

Unlike the Deutsch case and the Forman case, the Davids case was part of what was known as Wave I-C in the MDL court. On April 8, 2011, the MDL court remanded the Davids case back to this Court, with a number of motions pending. On April 21, 2011, this Court issued an order dismissing the pending motions without prejudice and with leave to re-file in

accordance with this Court's Individual Motion Practice Rules. (Docket Entry # 66.) The Court held a status conference on August 4, 2011, at which the Court authorized the parties to engage in limited damages discovery, and stated that Novartis had until November 7, 2011 to re-file any of the motions that had been previously pending before the MDL court.

On November 7, 2011, Novartis filed a motion for summary judgment seeking to dismiss the complaint in the Davids case in its entirety. Novartis also filed Daubert motions to exclude the testimony of the following experts who had previously been challenged in the MDL Court, as well as in the Deutsch and Forman cases: (1) Dr. Keith Skubitz; (2) Professor Wayne Ray; (3) Dr. Suzanne Parisian; (4) Dr. James Vogel; and (5) Dr. Robert Marx ("the Previously Challenged Experts"). The admissibility of the testimony of the Previously Challenged Experts was addressed by the MDL court, as well as in the Deutsch Daubert Order and Parisian Daubert Order. In addition, Novartis filed Daubert motions to exclude the expert testimony of Dr. Richard Kraut and the specific causation testimony of the Plaintiff's non-retained experts—including Dr. Salvatore Ruggiero, whose testimony on specific causation as a non-retained expert in the Deutsch case was addressed in the Deutsch Daubert Order.

Finally, both parties have submitted a number of motions *in limine* relating to issues that had not been previously pending before the MDL court. In particular, on March 12, 2012, Novartis filed a letter motion to preclude the Plaintiff's demand for punitive damages. This decision will only address those motions filed by Novartis on November 7, 2011, and in the following order: (1) the Daubert motions to exclude the Previously Challenged Experts; (2) the Daubert motion to exclude the expert testimony of Dr. Richard Kraut; (3) the Daubert motion to exclude the Plaintiff's non-retained experts; and (4) the motion for summary judgment. For the

caselaw applicable to the Daubert motions, the Court refers the parties to the law set forth in the Deutsch Daubert Order.

## II. DAUBERT MOTION TO EXCLUDE THE PREVIOUSLY CHALLENGED EXPERTS

Despite the clear, definitive rulings by both this Court and the MDL court, Novartis again moves to exclude the expert testimony in whole or in part of the following case-wide experts: (1) Dr. Keith Skubitz; (2) Professor Wayne Ray; (3) Dr. Suzanne Parisian; (4) Dr. James Vogel; and (5) Dr. Robert Marx. In response, by letter dated November 15, 2011, the Plaintiff stated:

> The Deutsch Daubert Order, issued by this Court, this year, on all these same experts, should simply be adopted. That is what precedent means. No fact in Ms. Davids' case makes anything the Court stated previously different or inapplicable. These witnesses are all case-wide experts. They have presented no case-specific opinions in Davids.

(Pl.'s Opp. at 1.) The Plaintiff further noted that most of the courts addressing the admissibility of the Plaintiff's case-wide experts have substantially adopted this Court's decision in the Deutsch Daubert Order. Finally, the Plaintiff emphasized that the Defendant's attempt to reargue the motion to exclude the testimony of Dr. Suzanne Parisian is particularly egregious in light of the fact that the Court held a two day Daubert hearing on the admissibility of Dr. Parisian's testimony.

In a letter response dated November 15, 2011, the Defendant argued that re-submitting the above motions was necessary in order to preserve the issues for appeal. Further, with respect to the merits of the motions and their similarity to those decided by the Court in the Deutsch Daubert Order, the Defendant stated:

> Obviously, this Court is aware of its rulings in Deutsch and Forman, but plaintiff's assertion ignores that, where *facts* are substantially different, such differences considerably alter the "fit" of each expert's proposed opinions under Daubert. Here,

> Novartis's briefs took considerable pains to point out the particular aspects of Ms. Davids's treatment and course of injury that differentiate this case from Deutsch and Forman. For example, as opposed to the clinical presentations in those cases, Ms. Davids experienced "spontaneous ONJ," in that it was not preceded by a dental procedure. This alone is a significant difference from the Deutsch and Forman cases. Whether each expert's opinions fit Ms. Davids's situation can be determined only be close review of the facts of this case. The Court should not be misled by the plaintiff's choice to ignore the differences in the cases that are highly germane under Daubert.

(Def.'s Reply at 1–2.) In addition, on March 23, 2012 and April 5, 2012, the Defendant submitted supplemental authority in support of its motion to exclude the testimony of Dr. Parisian.

It is not apparent to the Court what "considerable pains" the Defendant undertook to differentiate the Daubert motions in Davids from those that were before the Court in Deutsch and Forman. The most substantial difference between the Deutsch and Forman cases and the Davids case, is that Ms. Davids' allegedly developed spontaneous BRONJ, rather than BRONJ precipitated by a dental extraction. However, as with the motions previously before the Court, the Defendant primarily objects to each expert's methodology and qualifications to render opinions on particular issues of causation or the Defendant's conduct. Although the Court respects the Defendant's right to preserve all relevant issues for appeal, the Court sees no basis to deviate from its holdings in the Deutsch Daubert Order and subsequent Parisian Daubert Order with respect to the case-wide experts.

Accordingly, the Court adopts its rulings as set forth in the Deutsch Daubert Order and Parisian Daubert Order with respect to the admissibility of the expert testimony of: (1) Dr. Keith Skubitz; (2) Professor Wayne Ray; (3) Dr. Suzanne Parisian; (4) Dr. James Vogel; and (5) Dr. Robert Marx. To the extent any of these experts seek to render opinions on issues that are

unrelated to the facts of the Plaintiff's case, the Defendant may raise such objections at the trial. See Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 591, 113 S. Ct. 2786, 2795–96 (1993) ("Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.")

## III. DAUBERT MOTION TO EXCLUDE THE EXPERT TESTIMONY OF DR. RICHARD KRAUT

Novartis moves to exclude the general and specific causation testimony of Dr. Richard Kraut.

Dr. Kraut is a board-certified oral and maxillofacial surgeon. Dr. Kraut graduated in 1968 from the New York University School of Dentistry and completed his residency in Oral and Maxillofacial Surgery at the Fitzimmons and Brook Army Medical Centers. From 1988 to the present, Dr. Kraut has served as the Director of Oral and Maxillofacial Surgery at the Montefiore Medical Center/Albert Einstein College of Medicine. In 2003, Dr. Kraut became the Chairman of the Department of Dentistry at Montefiore Medical Center/Albert Einstein College of Medicine. Dr. Kraut has published extensively in his field; holds editorial positions as Senior Section Editor of the Journal of Implant Dentistry; and is a Reviewer for Oral Surgery, Oral Medicine, and Oral Pathology, as well as the Journal of Oral and Maxillofacial Surgery.

At trial, the Plaintiff seeks to offer Dr. Kraut's testimony that the Plaintiff suffers from "bisphosphonate related jaw necrosis". (Report at 4.) In reaching this conclusion, Dr. Kraut relied on: (1) his attendance at a December 2002 Harrigan Society Meeting at the NYU College of Dentistry where Dr. Ruggiero's case studies were presented and subsequent review of articles within the professional literature with regard to bisphosphonate caused jaw necrosis; (2) a letter to the editor by Dr. Robert Marx published in the Journal of Oral and Maxillofacial Surgery; (2)

an article by Dr. Salvatore Ruggiero published in 2004; (3) a series of position papers issued by the American Association of Oral and Maxillofacial Surgeons; and (4) his own personal experience treating more than ten patients with osteonecrosis of the jaw who have also taken IV bisphosphonate drugs. In addition, Dr. Kraut has authored two professional papers dealing with bisphosphonates.

With regard to the Plaintiff herself, Dr. Kraut reviewed: (1) the depositions of Dr. Perzov, Hoffman, Ruggiero, Sheehy-Milano, and Barbara Davids; (2) medical records from the Long Island Jewish Medical Center Dental Department; (3) medical records from Drs. Perzov and Ruggiero; (4) North Shore University Hospital Zometa Infusion Flow Sheets and X-ray; and (5) the Plaintiff's Fact Sheet and Supplemental Plaintiff's Fact Sheet. In addition, Dr. Kraut performed his own examination of the Plaintiff "and obtained a cone beam study, which shows dense bone in her mandible with no open bone". (Report at 4.)

First, Novartis contends that Dr. Kraut is not qualified to opine on bisphosphonate causation of ONJ because he is admittedly not an expert in oncology, bisphosphonates, toxicology, pharmacology, hematology, chemistry, or endocrinology.

"If the expert has educational and experiential qualifications in a general field closely related to the subject matter in question, the court will not exclude the testimony solely on the ground that the witness lacks expertise in the specialized areas that are directly pertinent." In re Zyprexa Prods. Liab. Litig., 489 F. Supp. 2d 230, 282 (E.D.N.Y. 2007) (citing Stagl v. Delta Air Lines, Inc., 117 F.3d 76, 80 (2d Cir. 1997)); Rupolo v. Oshkosh Truck Corp., No. 05-Cv-2978, 2010 WL 2244386, at * 4 (E.D.N.Y. June 01, 2010) ("In a product liability action, an expert witness is not strictly confined to his area of practice, but may testify concerning related

applications; a lack of specialization affects the weight of the opinion, not its admissibility.") (internal quotation marks and citation omitted).

Here, the Court finds that Dr. Kraut's lack of expertise in these areas identified by Novartis do not disqualify him from opining that the Plaintiff's ONJ was caused by bisphosphonates because Dr. Kraut does not purport to rely on such expertise as the basis for his opinion. Dr. Kraut is a highly-qualified oral and maxillofacial surgeon. Not only has Dr. Kraut demonstrated an expert understanding and familiarity with the research of the leading experts in BRONJ, but he has also performed his own bisphosphonate research. In addition, Dr. Kraut's expert opinions are influenced by his experience treating patients with ONJ that have also been exposed to both oral and IV bisphosphonates. Thus, the Court finds that Dr. Kraut is qualified to proffer opinions on general and specific causation under Daubert. See In re Fosamax Prods. Liab. Litig., 688 F. Supp. 2d 259, 268 (S.D.N.Y. 2010) (holding that the plaintiff's expert Dr. Redfern, was qualified to testify on BRONJ causation with respect to Fosamax because "[h]e has practiced dentistry for over 30 years; he specializes in oralfacial pain and maxillofacial radiology; he keeps up to date with the developments in research regarding BRONJ and has given presentations on the issue; he also has practical experience in that he has treated many patients that he believes developed ONJ from a bisphosphonate.").

Novartis seeks to exclude Dr. Kraut's general causation testimony on the ground that he relied on unreliable case reports or studies. Although Dr. Kraut's purported testimony was not the subject of a Daubert motion in either the Deutsch or Forman cases, the Court addressed this particular objection at length in the Deutsch Daubert Order and held:

> Novartis' objections to expert opinions on the grounds that they are unreliable because they rely on non-controlled epidemiologic studies or extrapolate opinions from articles based on different cancer types than those of Mrs. Deutsch and Mr. Napolitano will

> not affect the admissibility of such opinions. The weight of a conclusion derived from these studies involves the resolution of a factual dispute and therefore is a classic question for the jury.

768 F. Supp. 2d 420, 433–34 (E.D.N.Y. 2011). The Court adopts this holding as applied to Dr. Kraut's general causation testimony and therefore denies the Defendant's motion to exclude Dr. Kraut's general causation opinions.

Novartis also contends that Dr. Kraut relied on a flawed methodology in reaching his conclusions. The MDL court issued orders in four other Aredia/Zometa cases finding Dr. Kraut's qualifications and differential diagnosis methodology satisfied the Daubert requirement's to provide specific causation opinions that a plaintiff's use of Aredia or Zometa caused their ONJ. See In re Aredia and Zometa Prods. Liab. Litig. (Baldwin/Winter), 2010 WL 5139444 (M.D. Tenn. Dec. 7, 2010); In re Aredia and Zometa Prods. Liab. Litig. (Eberhart), 2010 WL 5072008 (M.D. Tenn. Dec. 7, 2010); In re Aredia and Zometa Prods. Liab. Litig. (McDaniel), 2010 WL 5071851 ((M.D. Tenn. 2010); In re Aredia and Zometa Prods. Liab. Litig. (Kyle/Mahaney), 2010 WL 5071063 (M.D. Tenn. 2010). Although under a different legal standard, the state court in Bessemer v. Novartis Pharmaceuticals Corporation, No. MID-L-1835-08 (N.J. Sup. Ct. April 30, 2010), also admitted the specific causation opinion Dr. Kraut based on his differential diagnosis methodology. The Court is equally persuaded and finds that Dr. Kraut's specific causation testimony is admissible.

Based on his review on his independent research into bisphosphonates, the materials he reviewed, and his own examination of the Plaintiff, Dr. Kraut performed a differential diagnosis. "A differential diagnosis is a patient-specific process of elimination that medical practitioners use to identify the most likely cause of a set of signs and symptoms from a list of possible causes." Ruggiero v. Warner-Lambert Co., 424 F.3d 249, 254 (2d Cir. 2005) (internal quotation

marks and citations omitted). "A medical expert's opinion based upon differential diagnosis normally should not be excluded because the expert has failed to rule out every possible alternative cause of a plaintiff's illness." Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 202 (4th Cir. 2001). However, even though "an expert need not rule out every potential cause in order to satisfy Daubert, the expert's testimony must at least address obvious alternative causes and provide a reasonable explanation for dismissing specific alternate factors identified by the defendant." Israel v. Spring Indus., Inc., 98-CV-5106, 2006 WL 3196956, at *5 (E.D.N.Y. Nov. 3, 2006).

As part of his differential diagnosis, Dr. Kraut ruled out the Plaintiff's "chemotherapy and radiotherapy . . . , corticosteroids, anemia, infection, preexisting oral disease, smoking which had ceased 18 years prior to the initiation of her jaw necrosis, moderate alcohol consumption, post herpetic neuralgia" and "other causes that have been suggested that do not seem relevant". (Report at 4.) Dr. Kraut did not simply dismiss these alternative causes offhand. Rather, he based his analysis on his knowledge of the prevailing literature; his own research; his personal experience treating patients who have taken Zometa and developed ONJ; his review of the Plaintiff's medical records; and his examination of the Plaintiff.

For example, Dr. Kraut ruled out radiation necrosis because Ms. Davids did not undergo radiation to her jaw. (Kraut Dep., 37:16–38:23). Dr. Kraut also ruled out osteomyelitis because of the fact that the necrosis appeared after long term bisphosphonate treatment; the Plaintiff's bone was exposed for over 2 months; and her exposed bone did not respond to the routine and usually successful osteomyelitis treatment. (Id., 42:14–20, 87:4–89:12). To the extent Novartis argues that Dr. Kraut did not adequately rule out additional factors or has provided contradictory testimony in the various depositions, these are credibility determinations that go to the weight

and not the admissibility of his opinions. See In re Fosamax Prods. Liab. Litig., 688 F. Supp. 2d at 269 ("Merck's objections to the soundness of Dr. Redfern's opinion are noted, but they do not lead the Court to conclude that there is such a large analytical gap between the medical records and his conclusion as to warrant exclusion. Cross-examination is the appropriate method for Merck to expose what it believes are flaws in Dr. Redfern's reasoning."); Bouchard v. Am. Home Prods. Corp., No. 98-CV-7541, 2002 WL 32597992 at *7 (N.D. Ohio May 24, 2002) ("The Court is not convinced that Dr. Manges' methodology is faulty. If Bouchard believes that he did not examine sufficient evidence to support his opinion, or believes that he ignored evidence that would have required him to substantially change his opinion, that is a fit subject for cross-examination, not a grounds for wholesale rejection of an expert opinion.").

Thus, the Court denies the Defendant's Daubert motion to exclude the specific causation testimony of Dr. Kraut.

## IV. MOTION TO EXCLUDE THE SPECIFIC CAUSATION OPINIONS OF THE PLAINTIFF'S NON-RETAINED EXPERTS

In the Plaintiff's Rule 26(A)(2)(a) statement submitted to the MDL court, the Plaintiff identified the following non-retained expert witnesses who may be called to testify at trial and provided the following description of their proposed testimony:

1. Dr. Salvatore Ruggiero, D.M.D. – "Dr. Ruggiero is one of Mrs. David's Oral & Maxilofacial surgeons. . . . He diagnosed Mrs. Davids with Stage 3 BRONJ and that her condition was caused by Zometa. He will testify to his treatment of her and may use his expertise in this testimony. He will testify to the link between bisphosphonates and ONJ. . . ."

2. Dr. Eileen Sheehy-Milano, M.D. – "Dr. Sheehy-Milano is an oncologist who treated Mrs. Davids. She will testify to her treatment of Mrs. Davids and may use her expertise in this testimony. She will testify that Zometa was stopped because of Mrs. Davids condition and her opinion that her ONJ was induced by bisphosphonates. . . . She will also comment on various conditions of Mrs. Davids that she treated. . . ."

3. Perry S. Perzov, D.D.S., FAGD – "Dr. Perzov was Mrs. Davids's dentist. He will testify as to her dental health and her experience with Osteonecrosis of the Jaw which he diagnosed and may use his expertise in his testimony. He will testify her condition was consistent with bisphosphonate Osteonecrosis of the Jaw. . . ."

4. Leonard Hoffman, D.D.S. – "Dr. Hoffman is Mrs. Davids's dentist. . . . He is expected to testify to his treatment of MRs. Davids and may use his expertise in doing so. He will describe Mrs. Davids's treatment and disease. He will testify there is a causal relationship between bisphosphonates and ONJ and that bisphosphonates caused Mrs. Davids ONJ. Further, he agrees with Dr. Ruggiero's diagnosis of BRONJ in Mrs. Davids. . . ."

5. Dr. Ronald E. Schneider, D.D.S. – "Dr. Schneider was Mrs. Davids's Oral Maxilofacial Surgeon. . . . He is expected to testify that Mrs. Davids has bisphosphonate ONJ. He is further expected to testify that it was caused by Defendant's drug. . . ."

As indicated above, the Plaintiff reserved her right to elicit specific causation testimony from each of her non-retained experts. As set forth below, with the exception of Dr. Ruggiero, the Court finds that the Plaintiff's non-retained experts are not qualified under Daubert to proffer specific causation opinions.

**A. Legal Standard for the Admissibility of Causation Opinions by Non-Retained Experts**

"It is well settled that a treating physician is not subject to the disclosure obligations set forth in Fed. R. Civ. P. 26(a)(2)(B)." Zanowic v. Ashcroft, No. 97-CV-5292, 2002 WL 373229, at *2 (S.D.N.Y. Mar. 8, 2002). "Generally, a treating physician may provide expert testimony regarding a patient's illness, the appropriate diagnosis for that illness, and the cause of the illness." Gass v. Marriott Hotel Servs., Inc., 558 F.3d 419, 426 (6th Cir. 2009) (emphasis added); Monroe v. Zimmer U.S. Inc., No. 08-CV-2944, 2011 WL 534037, at *17 (E.D. Cal. Feb. 14, 2011) (holding that because the plaintiff's treating physician was familiar with the plaintiff's medical history, he was "qualified to render opinion testimony on causation, diagnosis, or other matters based on his treatment of plaintiff").

However, when the treating physician seeks to render an opinion on causation, that opinion "is subject to the same standards of scientific reliability that govern the expert opinions of physicians hired solely for the purposes of litigation." In re Aredia and Zometa Prods. Liab. Litig. (Simmons), 754 F.Supp.2d 934, 936 (M.D. Tenn. 2010); Barrett v. Rhodia, Inc., 606 F.3d 975, 982 (8th Cir. 2010) ("[The treating physician's] opinion on causation is subject to the same standards of scientific reliability that govern the expert opinions of physicians hired solely for the purpose of litigation.") (internal quotation marks and citation omitted); Campbell v. CSX Transp., Inc., No. 08-CV-2045, 2009 WL 1444656 at *3 (C.D. Ill. May 21, 2009) ("[W]e do not distinguish the treating physician from other experts when the treating physician is offering expert testimony regarding causation.").

In addition, treating physicians who are designated as non-retained experts under Rule 26(a)(2)(A) are "not . . . permitted to render opinions outside the course of treatment and beyond the reasonable reading of the medical records." Lamere v. New York State Office For The Aging, 223 F.R.D. 85, 89 (N.D.N.Y. 2004); In re Aredia and Zometa Prods. Liab. Litig., ("Aredia Forman"), 2009 WL 2496859, at *2 (M.D. Tenn. Aug. 13, 2009) ("A treating physician for whom no expert report is supplied is not permitted to go beyond the information acquired or the opinion reached as a result of the treating relationship to opine as to the causation of an injury or give an opinion regarding the view of an expert called by the defendant.") (citing Lorenzi v. Pfizer, Inc., 519 F. Supp. 2d 742 (N.D. Ohio 2007)); Brundidge v. City of Buffalo, 79 F. Supp. 2d 219, 225 (W.D.N.Y. 1999) (permitting the plaintiff's treating physician to testify about "her opinion as to what caused plaintiff's mental problems as long as her opinion is based solely on her treatment of the plaintiff"). However, "most, if not all, courts that have considered this issue recognize that a treating physician often forms opinions and makes determinations during the

various stages of the course of treatment." Lamere, 223 F.R.D. at 89–90 (citing Santoro v. Signature Const., Inc., No. 00-CV-4595, 2002 WL 31059292, at *4 (N.D.N.Y. Sept. 16, 2002)).

**B. As to Dr. Schneider, Dr. Sheehy-Milano, Dr. Perzov, and Dr. Hoffman**

As an initial matter, the Plaintiff did not oppose the Defendant's motion to exclude the specific causation testimony of Dr. Ronald Schneider. Accordingly, the Court grants the Defendant's Daubert motion to exclude any testimony by Dr. Schneider with respect to specific causation.

Furthermore, the Plaintiff does not appear to dispute that Drs. Sheehy-Milano and Perzov are not qualified to testify as to the cause of the Plaintiff's BRONJ. (Pl.'s Opp. at 11.) Drs. Sheehy-Milano and Perzov testified that they are not experts in ONJ or its potential causes. (Sheehy-Milano Dep. at 28–29, 32–33; Perzov Dep. at 24, 71). In addition, Drs. Sheehy-Milano and Perzov testified that: (1) they either did not have an opinion regarding causation or that their opinion was based upon the diagnosis of others, (Sheehy Dep. at 94–95, 29; Perzov Dep. at 71–72) and (2) they did not perform a differential diagnosis as to the cause of the Plaintiff's jaw condition (Sheehy Dep. at 94; Perzov Dep. at 71–72). Thus, the Court finds that Drs. Sheehy-Milano and Perzov cannot testify as to the specific cause of the Plaintiff's jaw condition because they lack the requisite expertise and any such testimony would not be based on scientifically reliable or admissible methodologies.

In contrast to Drs. Sheehy-Milano and Perzov, the Plaintiff argues that Dr. Hoffman, her oral and maxillofacial surgeon, is qualified to render a specific causation opinion.

Dr. Hoffman is an oral maxillofacial surgeon who diagnosed BRONJ in the Plaintiff. The Plaintiff simply argues that Dr. Hoffman is qualified because he is an oral maxillofacial and, without any supporting evidence, displays expertise through his knowledge and training. (Pl.'s

Opp. at 11–12.) By contrast, Dr. Hoffman testified that he did not at the time and does not now consider himself "an expert in determining the cause of osteonecrosis of the jaw in patients who had been exposed to bisphosphonates". (Hoffman Dep. at 85:9–16.) The Court finds that, on this record, the Plaintiff has failed to meet her burden in showing that Dr. Hoffman is qualified to provide an expert opinion on specific causation.

Moreover, the Court also finds that Dr. Hoffman's methodology does not pass muster under Daubert. According to the Plaintiff "[Dr. Hoffman's] differential diagnosis was thorough and went over all the known factors before arriving at Zometa." (Pl.'s Opp. at 6.)

In describing his differential diagnosis, Dr. Hoffman stated:

> And my differential diagnosis included trauma to the local tissue. It included dental infection. It included other factors. I had to rule out other drugs, we talked about, or other medical conditions, such as uncontrolled diabetes and what have you, and all of these were ruled out.
>
> So without any other etiologic factor, and given the fact that in four months the lesion had not healed, we could rule out trauma to the local tissue. And the fact that she was a breast cancer patient taking Zometa, and that we now had anecdotal evidence that bisphosphonates could cause such a lesion. We then came to that conclusion, that it was a lesion of the bisphosphonate.

(Hoffman Dep. at 65:13–66:5.)). Dr. Hoffman also testified as to why he ruled out chemotherapy and radiation.

The Court finds it problematic that Dr. Hoffman does not identify the "other factors" or "other drugs" that he ruled out. These vague descriptions prevent the Court from determining whether Dr. Hoffman applied a reliable methodology in ruling out these unidentified causes. Moreover, while a differential diagnosis does not need to rule out every possible factor, Dr. Hoffman does not explain his basis for determining what factors were relevant to his analysis. "[W]here, as here, there is no indication that [Dr. Hoffman] made informed decisions to exclude

such factors based on any identifiable expertise or medical literature, such a differential diagnosis is scientifically unreliable under Daubert." Deutsch Daubert Order, 768 F. Supp. 2d at 475. Thus, the Court grants the Daubert motion by Novartis to exclude Dr. Hoffman's opinions on specific causation.

However, as the Court noted in the Deutsch Daubert Order, the exclusion of a treating physician's opinions on specific causation does not act as a bar to other relevant and admissible testimony "to the facts of [the Plaintiff's] symptoms, tests, diagnosis and treatment, as to what they did in response to [her] condition and as to what they would have done differently, if anything, had they known of any additional warnings.". Id. at 471 (citation omitted); see also id. at 475 ("However, there is nothing to prevent these treating physicians from testifying as to the facts about the presence of osteonecrosis of the jaw or the severity of the alleged alternative cause factors. In addition, these treating physicians can testify as to the facts regarding the treatment plans they administered. However, they cannot go as far as opining as to whether Aredia, Zometa, or other present factors were or were not the cause of Mrs. Deutsch and Mr. Napolitano's conditions, and whether their conditions were BRONJ.").

Thus, consistent with the Court's ruling on the admissibility of the Deutsch and Forman plaintiffs' non-retained experts in the Deutsch Daubert Order, this decision solely addresses whether the treating physicians may directly offer opinions on specific causation—i.e., whether Ms. Davids had bisphosphonate induced ONJ caused by the use of Zometa. To the extent that Novartis believes certain lines of questioning lead to an impermissible inference of causation, those objections may be raised at the trial.

**C. As to Dr. Salvatore Ruggiero**

Finally, Novartis also moves to exclude the specific causation testimony of Dr. Salvatore Ruggiero, one of the Plaintiff's treating physicians who was also one of Ms. Deutsch's treating physicians. As it did in the Deutsch case, Novartis challenges Dr. Ruggiero's qualifications as well as the methodology underlying his differential diagnosis. Nothing in the Defendant's present motion alters the Court's view that Dr. Ruggiero is "indisputably qualified" to provide a specific causation opinion. Deutsch Daubert Order, 768 F. Supp. 2d at 475.

With respect to his methodology, Dr. Ruggiero applied the same type of differential diagnoses in reaching his conclusions that Ms. Deutsch and Ms. Davids suffered from BRONJ. The Court agrees with the Defendant that it is problematic that Dr. Ruggiero purportedly "did not know that Ms. Davids had periodontal disease, that she had prior extractions while on bisphosphonates that healed without issue, or that she took Fosamax before, during, and after she received Zometa". (Def.'s Br. at 14.) However, as the Court noted in the Deutsch Daubert Order, the failure to rule out every possible cause does not render an opinion inadmissible.

Furthermore, the Second Circuit has held that "there should be a presumption of admissibility of evidence." Borawick v. Shay, 68 F.3d 597, 610 (2d Cir.1995); see In re Zyprexa Prods. Liab. Litig., 489 F. Supp. 2d 230, 282 (E.D.N.Y. 2007) (noting that "the assumption the court starts with is that a well qualified expert's testimony is admissible"); see also Lidle v. Cirrus Design Corp., No. 08–CV–1253, 2010 WL 2674584, at *4 (S.D.N.Y. July 6, 2010).

Dr. Ruggiero is an expert in the relationship between bisphosphonates and ONJ. He has performed case studies on the causal connection between bisphosphonates and ONJ and has personal experience treating a substantial number of patients who allege to suffer from BRONJ, including the Plaintiff. Based on the portions of deposition testimony submitted to the Court, the

Court does not find any grounds to conclude that Dr. Ruggiero made uninformed determinations as to what potential risk factors to rule out. To the extent that Novartis disagrees with what factors Dr. Ruggiero did and did not rule out, or with the records Dr. Ruggiero did or did not review, this is a proper subject for cross-examination. Thus, the Court denies the Defendant's Daubert motion to exclude the specific causation opinion of Dr. Ruggiero.

## V. MOTION FOR SUMMARY JUDGMENT

In the Third Amended Complaint, the Plaintiff alleges causes of action for (1) strict liability, (2) negligent manufacture, (3) negligent failure to warn, (4) breach of express warranty, and (5) breach of implied warranty. The Defendant has moved for summary judgment dismissing all the claims. In opposition to the instant motion, the Plaintiff voluntarily dismissed her cause of action for breach of express warranty. In addition, although the Defendant moves for summary judgment on a "negligence *per se*" claim, the Plaintiff states in her opposition that she has not asserted a claim for "negligence *per se*". Accordingly, the Defendant's motion for summary judgment as to the breach of express warranty claim is granted and the Defendant's motion for summary judgment as to the "negligence *per se*" claim is denied as moot. Thus, the Court will only address the Defendant's motion with respect to the remaining causes of action.

The Plaintiff does not appear to dispute that ONJ can develop spontaneously, without a precipitating invasive dental procedure. However, the parties heavily dispute whether BRONJ can develop absent the use of bisphosphonate drugs such as Zometa, and whether in fact the Plaintiff suffers from BRONJ. Consistent with the Court's rulings on the Daubert motions, these issues cannot be resolved on a motion for summary judgment. Nevertheless, the Defendant seeks summary judgment dismissing the Plaintiff's claims on the grounds that, even assuming she has BRONJ, there is insufficient evidence to support that: (1) Zometa was the specific cause

of her BRONJ; (2) the Defendant's actions were the proximate cause of her BRONJ; or (3) that her implied warranty claims are sufficiently distinct from her negligence claims to survive summary judgment.

**A. Legal Standard on a Motion for Summary Judgment**

It is well-settled that summary judgment under Fed. R. Civ. P. 56(c) is proper only "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The moving party bears the burden of establishing the absence of a genuine issue of material fact. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 256, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986). A fact is "material" within the meaning of Fed. R. Civ. P. 56 when its resolution "might affect the outcome of the suit under the governing law." Id. at 248, 106 S. Ct. 2505. An issue is "genuine" when "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Id. In determining whether an issue is genuine, "[t]he inferences to be drawn from the underlying affidavits, exhibits, interrogatory answers, and depositions must be viewed in the light most favorable to the party opposing the motion." Cronin v. Aetna Life Ins. Co., 46 F.3d 196, 202 (2d Cir.1995) (citing United States v. Diebold, Inc., 369 U.S. 654, 655, 82 S. Ct. 993, 8 L. Ed. 2d 176 (1962) (per curiam), and Ramseur v. Chase Manhattan Bank, 865 F.2d 460, 465 (2d Cir. 1989)).

Once the moving party has met its burden, "the nonmoving party must come forward with 'specific facts showing that there is a genuine issue for trial.'" Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587, 106 S. Ct. 1348, 89 L. Ed. 2d 538 (1986) (quoting Fed. R. Civ. P. 56(e)). However, the nonmoving party cannot survive summary judgment by

casting mere "metaphysical doubt" upon the evidence produced by the moving party. Matsushita, 475 U.S. at 586. Summary judgment is appropriate when the moving party can show that "little or no evidence may be found in support of the nonmoving party's case." Gallo v. Prudential Residential Servs., 22 F.3d 1219, 1223–24 (2d Cir. 1994) (citations omitted).

**B. As to Specific Causation**

The Defendant contends that the Plaintiff's claims must fail because she cannot establish specific causation, which is a required element for all her claims. See Heckstall v. Pincus, 19 A.D.3d 203, 797 N.Y.S.2d 445, 447 (1st Dep't 2005).

First, the Defendant argues that the Plaintiff has failed to meet her evidentiary burden to defeat a summary judgment motion on specific causation because the opinions of Dr. Ruggiero and Dr. Kraut are inadmissible under Daubert. However, as set forth above, the Court has denied the Defendant's motions to exclude the specific causation opinions of Dr. Ruggiero and Dr. Kraut, and held that the Defendant's objections go to the weight and not the admissibility of their opinions. Whether Dr. Ruggiero and Dr. Kraut's testimony is credible is an issue of fact for the jury to decide and thus inappropriate for resolution on a motion for summary judgment.

Next, the Defendant argues that, even assuming Dr. Ruggiero and Dr. Kraut's testimony is admissible, and assuming that the Plaintiff has BRONJ, the Plaintiff cannot prove that Zometa was the specific cause of her BRONJ. In support of this contention, the Defendant cites to Gayle v. City of New York, where the New York Court of Appeals held that, in the context of showing the proximate cause of an accident

> the proof must render those other causes sufficiently 'remote' or 'technical' to enable the jury to reach its verdict based not upon speculation, but upon the logical inferences to be drawn from the evidence . . . A plaintiff need only prove that it 'more likely' or 'more reasonable' that the alleged injury was caused by the defendant's negligence than by some other agency.

92 N.Y.2d 936, 937, 680 N.Y.S.2d 900, 901, 703 N.E.2d 758, 759 (1998) (citations omitted)

Here, Dr. Ruggiero testified that, although he did not include Fosamax in his differential diagnosis, he views Fosamax as causing BRONJ at a lower incidence rate than IV bisphosphonates such as Zometa. (Ruggiero Dep. 38:16–19.) In addition, Dr. Kraut testified that he did not consider Fosamax as part of his differential diagnosis because "he wasn't paying attention to it" and "the potency of the drug in relation to Zometa would have caused me to focus on the Zometa . . .". (Kraut Dep. 35:2–12.).

The Defendant argues that, because the Plaintiff also took Fosamax, an oral bisphosphonate that has also been linked to ONJ, and because neither Dr. Ruggiero nor Dr. Kraut ruled out Fosamax as a cause of the Plaintiff's BRONJ in performing their differential diagnoses, the Plaintiff cannot show that it is "more likely or more reasonable" that her ONJ was caused by Zometa. However, the fact that Dr. Ruggiero and Dr. Kraut did not "rule out" Fosamax is not equivalent to the absence of a genuine issue of material fact with respect to specific causation. As the Court of Appeals noted in Gayle, "the Appellate Division erred in determining that plaintiffs were required to rule out all plausible variables and factors that could have caused or contributed to the accident". 92 N.Y.2d at 937, 680 N.Y.S.2d at 901, 703 N.E.2d at 759.

Although Drs. Ruggiero and Kraut did not "rule out" Fosamax, drawing all inferences in the Plaintiff's favor, their above-cited testimony creates a genuine issue of material fact as to whether Zometa was the "most likely or more reasonable" cause of the Plaintiff's jaw condition. "Where a defendant raises alternative causes to avoid liability for a product's failure, a plaintiff raises a triable question of fact by offering competent evidence which, if credited by the jury, is sufficient to rebut defendant's alternative cause evidence." Steinman v. Spinal Concepts, Inc., No. 05-CV-774, 2011 WL 4442836, at *7 (W.D.N.Y. Sept. 22, 2011) (internal quotation marks

and citations omitted). Here, the Plaintiff has offered sufficient evidence that Zometa caused her to develop BRONJ, which could be credited by a jury. Whether and to what extent the Plaintiff's use of Fosamax was a factor in the development of her ONJ requires a fact-specific inquiry and expert credibility determinations that are inappropriate on a motion for summary judgment. Thus, the Court denies the Defendant's motion for summary judgment on specific causation.

**C. As to Proximate Causation**

Novartis also seeks summary judgment on the ground that, assuming the Plaintiff developed BRONJ from her use of Zometa, there is no evidence to support that the Defendant's actions were the proximate cause of her injury. As a result, Novartis seeks summary judgment on the Plaintiff's negligent manufacture, negligent failure to warn, and strict liability causes of action.

"Where liability is predicated on a failure to warn, New York views negligence and strict liability claims as equivalent." Martin v. Hacker, 83 N.Y.2d 1, 8 n. 1, 607 N.Y.S.2d 598, 601, 628 N.E.2d 1308 (1993). "For claims of strict products liability, negligence, or breach of an implied warranty, 'the plaintiff must prove that the product was defective as a result of either a manufacturing flaw, improper design, or a failure to provide adequate warnings regarding use of the product.'" Adesina v. Aladan Corp., 438 F. Supp. 2d 329, 345 (S.D.N.Y. 2006) (quoting Langer v. Well Done, Ltd., No. 05-CV-7491, 2006 WL 462125, at *2 (N.Y. Sup. Ct. Jan. 31, 2006). Here, the Plaintiff primarily basis her claims on the Defendant's failure to provide adequate warnings.

"A plaintiff proceeding under a failure-to-warn theory in New York must demonstrate that the failure to warn adequately of the dangers of a product was a proximate cause of his or

her injuries." Bravman v. Baxter Healthcare Corp., 984 F.2d 71, 75 (2d Cir. 1993) (citing Glucksman v. Halsey Drug. Co., Inc., 160 A.D.2d 305, 307, 553 N.Y.S.2d 724, 726 (1st Dep't 1990). "Whether the cause of action for failure to warn is based on negligence or strict liability, the courts of this state have consistently held that a manufacturer's duty is to warn only of those dangers it knows of or are reasonably foreseeable". Mulhall v. Hannafin, 45 A.D.3d 55, 58, 841 N.Y.S.2d 282, 285 (1st Dep't 2007). "Under New York law, a defense is provided against liability for failure to warn when a drug or medical device is "'properly prepared, and accompanied by proper directions and warning.'" Martin v. Hacker, 83 N.Y.2d 1, 8, 607 N.Y.S.2d 598, 601, 628 N.E.2d 1308 (1993) (quoting Wolfgruber v. Upjohn Co., 72 A.D.2d 59, 61, 423 N.Y.S.2d 95, 97 (4th Dept.1979), aff'd., 52 N.Y.2d 768, 436 N.Y.S.2d 614, 417 N.E.2d 1002 (1980) (quotation and citation omitted)). The manufacturer satisfies its duty by "warn[ing] of all potential dangers in its prescription drugs that it knew, or, in the exercise of reasonable care, should have known to exist." Sita v. Danek Medical, Inc., 43 F. Supp. 2d 245 (E.D.N.Y. 1999) (quoting Martin, 83 N.Y.2d at 8, 607 N.Y.S.2d at 601).

Under the "learned intermediary rule" the manufacturer of a prescription drug does not have a duty to warn the patient of the dangers involved of the product, but rather the duty is owed to the patient's doctor. See Bravman v. Baxter Healthcare Corp., 984 F.2d 61, 75 (2d. Cir. 1993); Lindsay v. Ortho Pharm. Corp., 637 F.2d 87 (2d. Cir. 1980).The basis for this rule is that "[t]he doctor acts as an "informed intermediary" between the manufacturer and the patient, evaluating the patient's needs, assessing the risks and benefits of available drugs, and prescribing and supervising their use." Glucksman v. Halsey Drug Co., Inc., 160 A.D.2d 305, 553 N.Y.S.2d 724 (1st Dep't 1990).

"Failure to warn law includes a presumption that a user would have heeded warnings if they had been given, and that the injury would not have occurred." Adesina, 438 F. Supp. 2d at338 (internal quotation marks and citation omitted). The Defendant "may rebut this presumption by introducing specific facts showing that the warning would have been futile." Id. (citation omitted). "If a failure to warn would have been futile, [the Plaintiff] cannot prove proximate causation." Id.

As an initial matter, the Court finds that, even assuming Novartis had a duty to warn the dental community of the risks associated with Zometa, the Defendant has introduced sufficient facts to show that warning the Plaintiff's dentist, Dr. Perzov, or her oral and maxillofacial surgeons, Drs. Hoffman, Schneider, or Ruggiero would have been futile because they would not have impacted her risk of developing BRONJ.

Although a prescribing physician's course of conduct is a relevant issue, other courts have recognized that proximate causation can be satisfied for purposes of the learned intermediary doctrine where a non-prescribing physician testifies that the physician was aware of the patient's use of a given drug and would have recommended taking the patient off of that medication if a different warning had been given. See Golod v. La Roche, 964 F. Supp. 841, 857 (S.D.N.Y.1997) ("In addition, Dr. Oksman, Golod's ophthalmologist since 1988, knew that she was taking Tegison and has indicated that he would have recommended that she cease using the drug if the PDR had warned of the risk of permanent ocular adverse effects. Thus, even if Dr. Grossman would have continued prescribing Tegison, another of Golod's physicians would have recommended that she stop."). Here, Dr. Perzov testified that the Plaintiff did not disclose that she was taking Zometa, or any other bisphosphonate drug, until after she allegedly developed ONJ. Thus, there is no admissible evidence from which a reasonable jury could conclude that

Dr. Perzov was aware that the Plaintiff was on Zometa prior to 2005, and the assertion that Dr. Perzov would have warned her to stop taking Zometa if Novartis had included a warning to the dental community is purely speculative. In addition, Drs. Hoffman, Schneider, and Ruggiero did not begin treating the Plaintiff until after she had allegedly already developed BRONJ. Thus, the Court grants the Defendant's motion for summary judgment on the Plaintiff's failure to warn claim to the extent the failure to warn claim is predicated on the Defendant's failure to warn the dental community.

In addition, the Defendant generally argues that the September 2003 label and the September 24, 2004 Dear Doctor letter adequately warned the Plaintiff's oncologist, Dr. Sheehy-Milano, of the risk of ONJ in patients using Zometa. However, the Court agrees with the MDL court, and the majority of other courts to address this issue, that based on the expert testimony submitted by the Plaintiff, whether the labels and other warnings adequately warned the Plaintiff's oncologist is an issue of fact for the jury.

Nevertheless, according to Novartis, assuming the Plaintiff did develop BRONJ, it was spontaneous and unrelated to dental extractions or procedures. As a result, Novartis argues that neither the guidelines for pre-bisphosphonate therapy dental treatment, or a warning to avoid dental extractions, would have prevented the development of her ONJ. This argument is supported by the testimony of Dr. Ruggiero and Dr. Kraut, who both describe the Plaintiff as having "spontaneous" BRONJ and note that warnings with respect to dental extractions would not have prevented her injury.

At this stage, the Court does not need to reach the issue of whether the Plaintiff's BRONJ was "spontaneous" and therefore whether warnings regarding dental extraction would have prevented her injury. This is because, even assuming her BRONJ did develop "spontaneously"

so that warnings regarding dental extractions would not have prevented her injury, the Plaintiff claims that the risk of developing BRONJ is not solely caused by dental extractions, but can be severely reduced by preventitve dental care. As stated in the Deutsch Daubert Order, and adopted here, the Court finds the testimony of the Plaintiff's experts Drs. Marx, Skubitz, and Vogel admissible with respect to the theory that preventative measures, including pretreatment dental screening, may decrease the risk of BRONJ. See Deutsch Daubert Order, 768 F. Supp. 2d 420, 437–38 (E.D.N.Y. 2011). To the extent that pretreatment dental screening would have revealed that the Plaintiff was at a higher risk of developing BRONJ, whether spontaneously or not, so that it would have altered whether she took Zometa in the first place, requires credibility determinations and a fact-specific inquiry that are properly left to the province of the jury.

Thus, contrary to the Defendant's contention, even assuming the Plaintiff's BRONJ was spontaneous, the fact that warnings regarding dental extractions would not have prevented her injury does not defeat the proximate causation issue.

The Plaintiff's theory of causation requires her to present some evidence that if she had been warned about the risk of ONJ she would have discontinued using Zometa and thereby reduced her risk of contracting ONJ. Here, there is an issue of fact with respect to whether, had she received different warnings, Dr. Sheehy-Milano would have prescribed Zometa to the Plaintiff. In support of their motion, the Defendant provides a one-page excerpt from Dr. Sheehy-Milano's deposition where Dr. Sheehy-Milano gives the following testimony:

> Q. With that knowledge, not knowing whether ONJ would have occurred in Ms. Davids' case but putting yourself back at that time, would you still have recommended Zometa for Ms. Davids?
>
> A. Yes.

(Sheehy-Milano Dep. at 62:4–8.) The Defendant contends that this is indisputable evidence that, regardless of whether she received a different warning, Dr. Sheehy-Milano would have still

prescribed Zometa to Ms. Davids, and thus the Plaintiff cannot show that inadequate warnings proximately caused her injury. However, as indicated on the top of the same deposition page, this excerpt is derived from a "hypothetical" posed to Dr. Sheehy-Milano. Neither party provided the Court with the preceding page presumably setting forth the context for this statement. Furthermore, as the Plaintiff notes, Dr. Sheehy-Milano also testified that the benefits of Zometa do not outweigh the risks in patients that have problems "with the dental area", and further testified:

> Q. If the patient does have a problem with the dental area, what do you tell them?
>
> A. That this is a risk and they need to get cleared by their dentist.
>
> Q. So, you send them to a dental professional to, maybe, shape up their mouth before they begin taking Zometa, is that correct, or—
>
> A. Yes.

(Sheehy-Milano Dep. 63:9–23.) The Plaintiff claims that, based on the fact that Dr. Sheehy-Milano discontinued the Plaintiff's Zometa treatment and that her practice today is to have her patients checked by a dental professional before beginning Zometa therapy, "[t]he clear inference is that Dr. Sheehy-Milano would not have prescribed Zometa to Ms. Davids in the first place". (Pl.'s Opp. at 17). Both parties dispute the interpretation of Dr. Sheehy-Milano's testimony, and neither provide the Court with the appropriate context to resolve such a dispute on a motion for summary judgment. Thus, drawing all inferences in favor of the non-moving party, the Court finds that there is a genuine issue of material fact with respect to whether, had Dr. Sheehy-Milano received different warnings, she would have prescribed Zometa. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986) ("The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor.").

Furthermore, Dr. Sheehy-Milano also testified that it is ultimately the patient's decision as to whether they want to receive Zometa therapy despite the risk, and had she been aware of the risk of jaw necrosis, she would have discussed that risk with the Plaintiff. (Sheehy-Milano Dep. at 62,69.) The Plaintiff testified that, had she been aware of the risk, in light of her dental history, she would not have taken Zometa. (Davids Dep. at 132:20–133:2.)

Thus, the Court finds that the Plaintiff has sufficiently established genuine issues of material fact as to whether different warnings would have made a difference in her behavior, or the behavior of her treating physician, and therefore whether the Defendant's failure to warn was the proximate cause of her injury. Accordingly, the Defendant's motion for summary judgment dismissing the Plaintiff's negligent manufacture, negligent failure to warn, and strict liability claims is denied.

**D. As to the Breach of Implied Warranty Cause of Action**

Finally, Novartis contends that it is entitled to summary judgment on the Plaintiff's breach of implied warranty cause of action because the claim is not "independently cognizable" from her tort claims. However, the Defendant cites no caselaw for the proposition that a Court must dismiss a claim for breach of implied warranty that is predicated on the "same evidence and allegations" as the tort claims. (Def.'s Br. at 15.)

"[A]lthough the [tort] and implied-warranty claims are not identical under New York law, to what extent they are duplicative remains 'unsettled.'" Davila v. Goya Foods, Inc., No. 05-CV-8067, 2007 WL 415147, at *1 n.1 (S.D.N.Y. Feb. 7, 2007) (citing Jarvis v. Ford Motor Co., 283 F.3d 33, 62-63 (2d Cir. 2002); see also Denny v. Ford Motor Co., 87 N.Y.2d 248, 259, 639 N.Y.S.2d 250, 263, 662 N.E.2d 730, 739 (1995) ("[I]t is apparent that the causes of action

for strict products liability and breach of implied warranty of merchantability are not identical in New York and that the latter is not necessarily subsumed by the former.").

Neither party sufficiently addressed the separate legal theories underlying the two claims, and therefore the Court declines to rule at this stage of the litigation on whether the Plaintiff can separately maintain her tort and breach of implied warranty causes of action. Furthermore, to the extent her implied warranty cause of action is also based upon the alleged failure to warn, consistent with the Court's rulings above, there are genuine issues of fact precluding the Court from granting summary judgment on the Plaintiff's breach of implied warranty claim. Thus, the Defendant's motion to dismiss the Plaintiff's breach of implied warranty claim is denied.

## VI. CONCLUSION

This opinion constitutes the Court's rulings on the Defendant's Daubert motions and the Defendant's motion for summary judgment. The Court has considered all other arguments by the parties and finds them to be without merit.

**SO ORDERED**.
Dated: Central Islip, New York
April 19, 2012

*/s/ Arthur D. Spatt*
ARTHUR D. SPATT
United States District Judge